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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/069,703	04/29/1998	GILLES H. TAPOLSKY	VIRO:034	3665

7590 03/27/2007
A James Nelson ESQ
Schwegman Lundberg Woessner & Kluth
1600 TCF Tower
121 South Eighth Street
Minneapolis, MN 55402

EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/069,703	Applicant(s) TAPOLSKY ET AL.	
	Examiner Edward J. Webman	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10,12,13,15-18,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10, 12-13, 15-18, 33-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Prosecution is reopened in view of new issues regarding 35 USC 112:

Claims 1-3, 5-7, 12-13, 15-18, 33-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for water-erodible film forming polymers, does not reasonably provide enablement for any film forming polymer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. On page 11 lines 7-8 applicants disclose water-erodible film forming polymers. However, they claim any film forming polymer, including water-soluble polymers. For example Takayanagi et al disclose hydroxypropyl cellulose, polyvinyl alcohol, and gelatin as water-soluble (column 2 lines 58-68). Applicants claim these polymers as film-forming polymers in claim 3. Takayanagi et al also disclose starch, xanthane gum, karaya gum, sodium alginate, and agar-agar as water-soluble (column 2 lines 58-68). Applicants claim polysaccharides as film forming polymers in claim 3, which include water soluble polysaccharides such as those disclosed in Takayanagii et al. It appears that applicants are limited to the water-erodible forms of such polymers. For example, Takayanagi et al disclose that the highly substituted hydroxypropyl cellulose is water soluble (column 2 lines 66-67) whereas the low substituted polymer is water-swelling (column 3 lines 3-5).

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Claims 1-3, 5-7, 12-13, 15-18, 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As described above, applicants disclose film-forming polymers which can be water-soluble. Takayanagi et al disclose polyvinyl pyrrolidone, and carboxymethyl cellulose as soluble (column 2 lines 58-68). Applicants claims these polymers as bioadhesives in claim 3. Takayanagi et al also disclose carboxyvinyl polymer and sodium polyacrylate as soluble (column 2 line 58-68). Applicants claim polyacrylic acid, the acid form of sodium polyacrylate and a type of carboxyvinyl polymer. Thus, all three of the bioadhesive polymers in claim 3 can be adhesive. As discussed in the 112^{1st} paragraph rejection *supra*, some of the film-forming polymers in claim can also be water-soluble. In the case where both film-forming and bioadhesive polymers are water-soluble, a contradiction arises between the claimed water-erodible layer and the case where both polymers forming that layer are water-soluble. It appears that at least one of the polymers must be water-erodible.

Claims 10, 13, 16-18, 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for water-erodible devices, does not reasonably provide enablement for any device. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. On page 8 line 8 applicants disclose water-erodible devices. No others are specified.

Claims 10, 13, 16-18, 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 13, 16, 17, and 33 claim two water-erodible layers. However, it is unclear as to whether the entire device is water-erodible. Applicants do not so indicate (compare claims 1, 17 and 34).

Claims 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants claim a water-erodible film, however, applicants claim that this film comprises two water-soluble layers. There appears to be a contradiction. It is unclear as to how the film can be water erodible when the layers it comprises are water-soluble. Do applicants intend both layers to be water-erodible, as in independent claims 1, 10, 13, 16, 17, and 33?


No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500